Thank you for allowing me to testify today.

I am Dr. Richard Carchman .....

OSHA's responsibility in this proposed rule making is to demonstrate utilizing the best available date whether there is a material impairment to health due to exposure to ETS in the workplace to nonsmokers. The best available data should have at least the following properties:

A.   actual workplace measurements of the agent(s) of interest;

B.   health endpoints of the study population in the workplace; and

C.   adjustment for confounders and smoking misclassification.

Surrogates for A and B should only be used in the absence of such data. If a careful examination of the proposed rule making notice is undertaken, it is clear that OSHA has consistently failed in using the best available data for their analysis of material impairment to health. What OSHA has used instead are poor, and often inappropriate surrogates for their analyses. Inferences and conclusions drawn from a failure to use the best available data must be seriously questioned, deemed flawed and discarded. We have provided in our written response to this notice of proposed rule making, numerous examples of OSHA's misquotes, miscites, calculation errors and/or misrepresentations of the actual calculated values. There are also instances of providing no citations for important statements or conclusions and many instances of representing a citation with respect to the authors' own conclusions inappropriately.

I will now provide some of the most serious examples of OSHA's failure to use the best available data and several of the outcomes if the best available data are used. In addition, I will provide an example of how OSHA mischaracterized the numerical values from their lung cancer attributable lifetime risk where OSHA failed to meet their standard for agency action. (i.e. 1 in 1000).

OSHA relied on the use of self reporting activity studies in order to evaluate the extent of worker exposure. It is obvious from a careful reading of these documents that OSHA has selectively extracted and/or ignored data from these studies for the purpose of their rule making. One of the studies reported

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(undated National Health Study - CDP&P) lower nonsmoker exposure than OSHA concluded. OSHA dismisses this study result because it is "based solely on self reported information," a criticism which applies to all the studies OSHA utilized in this section.

OSHA did not address the reported trends in workplace smoking restrictions that have accelerated in recent years. The obvious impact of this on the number and extent to which workers are allowed to smoke, or ventilation quality at the workplace, OSHA does not address these at all. Unfortunately, this lack of information does not permit the use of the limited and selectively derived data OSHA uses to appropriately attribute lifetime risk. Table V, Tab 4 of Philip Morris' written submission provides over one dozen published studies on actual workplace measurements. These studies plus the Oak Ridge National Laboratory (ORNL) data presented to OSHA provide the following conclusions and insights:

1) workplace exposure is much lower than exposure at home (e.g. ORNL data calculate difference to be a factor of 5).

2) worker questionnaire data on worker exposure to ETS grossly overestimates actual exposure.

3) worker exposure to ETS has not remained constant over time.

These three conclusions alone are critical to underscore the very tenuous nature of OSHA's use of questionnaire data to judge exposure and OSHA's assumption that the relative exposure at home equals the exposure level in the workplace. These failures in OSHA's arguments undermine how OSHA used the Fontham, et al. (1994) and Helsing (1988) studies to calculate attributable risk. In addition, there are a number of key elements that OSHA did not consider in the use of the Fontham, et al. (1994) study as the sole source of date to calculate the lung cancer risk.

1. cotinine values 54% - author comment underestimating smoker misclassification.

2. Los Angeles and San Francisco - air pollution was not adjusted for.

3. representativeness of and the generalization of these workers to US workplaces are problematic.

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- >70% of the study population was $\geq$ 60 years of age.
- Low socioeconomic status. More than 40% of the population studied made less than $20,000 per year. Thirty-three percent had less than or equal to a high school education.
- Only females were studied.

4. significant lung cancer confounders were not presented. e.g. dietary fat intake where the relative risk for lung cancer is approximately 10.

5. the dramatic shift in relative risk is not discussed even though it was remarkable/unexpected/unique.   ?

6. If the pipe and cigar smoking is eliminated, the lung cancer risk   ? attributable to environmental tobacco smoke becomes non significant.   ,

Table 1, tab 5 of the Philip Morris submission, contains nine workplace ETS lung cancer studies conducted in the Untied States including Fontham, et al. (1994). Only one other study (2/9) had a statistically significant reported increase risk in lung cancer. The other study, Kabat and Wynder (1984), reported an increase in males, not females for lung cancer risk. Fontham, et al. (1994) claims an increase in females. In a subsequent study in 1990, the American Health Foundation, looked at a larger study population than in their 1984 study. They could not reproduce their effects in males, females remained non significant.

It is difficult to imagine how even a reasonable reading of the workplace/ETS/ Lung Cancer risk data which has been published can support the argument of causality and significant material impairment to health. Even if one ignores the shortcomings described above, and uses OSHA's assumptions of exposure (P_e) and the Fontham, et al. (1994) data in the equation OSHA published in their rule making notice; one can not obtain the values of lifetime occupational risk reported in Table IV-10. [0.4-1]. In fact, in the text OSHA refers to this table in a qualitative fashion "workers exposed to ETS, approximately one in one thousand will most likely develop lung cancer." Instead of 0.4-1, the actual reported numbers should be 0.32 -0.77. The implications of this include the use of novel numerical rounding procedures by OSHA, and a failure by OSHA to achieve the agency action level of one in one thousand. In addition, if one factors in the real proportion of workers in the United States exposed to ETS and that workplace exposure may be at least five fold less than home exposure, contrary to OSHA's assumption of parity, the appropriately calculated value will be several fold lower

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than OSHA has indicated. In conclusion, if OSHA follows its guidelines and uses all the correct lung cancer data in their attributable risk calculations, or accurately represents the true lifetime lung cancer risk calculations, OSHA has only one recourse and that is to conclude that ETS exposure in the workplace does not represent a significant impairment to health.

OSHA's conclusion that ETS exposure in the workplace poses a significant risk for cardiovascular disease is not supported by the published literature (whether or not it is cited or miscited by OSHA). OSHA's use of the Helsing study brings into question whether OSHA used the best available data in order to conclude and then derive from this data that 1) ETS exposure in the work places poses a significant impairment to health and 2) OSHA calculates a 7-16/1000 lifetime occupational risk. The Helsing (1988) study does not represent the best available data for a numbers of reasons:

1)   Spousal smoking;

2)   residential exposure (questionnaire)

3)   12 year gap, many assumptions on continuity and no change;

4)   did not control for confounding "...differences could influence our findings"

5)   smoker misclassification;

6)   non representative of US population - one county in one state.

There are three published studies available which contain workplace exposure and cardiovascular disease information. OSHA cites these studies in their notes; however, they mischaracterize their results.

The three studies of interest include:

1)   Dobson et al. (1991)

2)   Lee, et al. (1986)

3)   Svendsen, et al. (1987)

As an example of OSHA's misrepresentation in supporting their argument with respect to CVD and workplace ETS exposure, they list the Dobson, et al. (1991) study as a positive study. OSHA's conclusion must be based on something other than what the authors report or conclude. They state, "...passive smoking did not suggest increased risk." These numbers (OR) and quote are the authors. It

is unfathomable how OSHA can categorize this study as a positive association. The remaining two studies (Lee, et al., (1986) and Svendsen, et al. (1987)) did not report any significant risk in the workplace to ETS exposure. In a manuscript submitted for publication by LeVois and Layard, data from the American Cancer Society (CPS 1 & 2), and the National Mortality Followback study are utilized. This data failed to demonstrate any significant increase in CHD in either males or females. Numerically, this later study contains more subjects than all of these cited by OSHA combined. Using the best available data appropriately and accurately, OSHA should have concluded that with respect to ETS exposure and cardiovascular disease in the workplace, there is no material impairment to health.

In the event that OSHA's conclusion that ETS exposure in the workplace with respect to cardiovascular disease is upheld, several interesting absurdities could very well result. There have been reported in the literature several hundred risk factors for CVD that are equal to or greater than that reported by OSHA for ETS. (See RAC Table I). This table represents just some of these risk factors. to make my point, carbon monoxide has been shown to be a significant risk factor for cardiovascular disease, it represents a risk to the same extent as reported by OSHA for ETS. This significant risk associated with CO occurs at 50 ppm, OSHA's current PEL. Will OSHA regulate carbon monoxide as it proposes to regulate ETS in the workplace? This could result in the entire workplace being separately ventilated. Will OSHA be compelled to do this (regulate CO like ETS)? Will it be compelled to regulate coffee consumption in the workplace, the food in the cafeteria? Just a simple review of this information provides for a frightening prospect for the future of potential areas for OSHA to regulate based on the precedent OSHA is trying to establish with respect to its proposed rule making on ETS.

OSHA has clearly failed to satisfy its own guideline requirements in its characterization of the purported material impairment to health to nonsmokers associated with ETS in the workplace. OSHA's proposal is inconsistent with its own standards setting for current workplace exposures. OSHA's rule making with regard to ETS abandons the workers' real and serious exposures in the workplace by trying to set a separate rule making for ETS instead of an overall indoor air quality standard. This OSHA rule, if enacted, will have severe

repercussions in our society. The extension of this rule could be applied to banning or restricting coffee in the workplace, setting an absurd standard for carbon monoxide, restricting minority ethnic groups from the workplace, etc. These absurd outcomes are all based on published data that indicate that these, among many other factors, have significant risks for disease equal to or much greater than that used by OSHA to ETS. Is it possible that someone smoking in a work environment could close down the facility, create a dead zone that would require technicians in space suites to clean the area? Could this happen in the home? The answer to these questions is clearly yes. The overall implications to our society should be measured against the costs to true worker protection and not by politically correct initiatives. The possible ramifications of further governmental intrusions into our daily lives will be inevitable. The further degradation of our ability to compete in the world market would increase. It would appear that this attempt by OSHA to foist upon us all this de facto smoking ban more than just ignores any real IAQ concerns in the workplace, it allows the spread of the use of poor science at a time when all taxpayers should be demanding better use of their hard earned money.

WORKPLACE EXPOSURE

OSHA	BEST AVAILABLE DATA
4 - Indirect activity	14 published workplace measurment studies
Questionnaire studies	ORNL 16 cities study
	Omits EPA 1993 CAPS

OUTCOMES:

- Questionnaire data invalid
- Home ≠ Workplace
- Workplace exposure $\leq$ 5 times lower than home exposure
- Extent of worker exposure exaggerated
- Inflates OSHA attributable risk calculation

1

LUNG CANCER

OSHA

Fontham, et al. (1994)
Females only
LA/SF/Air pollution confounders
Representativeness
No Dose - Response
Cigars/Pipes

BEST AVAILABLE DATA

8 other US workplace studies
Only one of 8 shows a significance only
in males, not females
Same authors > 6 years not significant
in males or females

OUTCOMES:

- Use of single study
- Even using the OSHA calculation does not meet agency's action level of 1 in 1000.

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CARDIOVASCULAR DISEASE

OSHA	BEST AVAILABLE DATA
Helsing (1988)	Dobson, et al. (1991)
Spousal smoking	Lee, et al. (1986)
Residential	Svendsen, et al. (1987)
Confounders	NS workplace effects in all three studies
Misclassification	ACS CPS 1 & 2 NHFS - NS
Questionnaire exposure	Largest study population
12 year group	

OUTCOMES:

- Significant risk using Helsing data
- NS risk using best available data
- Opens workplace to dozens of regulations with other risk factors demonstrating the absurdity of OSHA's thinking.

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OSHA PRELIMINARY QUANTITATIVE RISK ASSESSMENT

Relative risk, RR	1.34
Extent of exposure rel. to home	1.00
Corrected relative risk, RRc:	1.3400
Incidence in total population Ip:	0.0001210
Proportion of exposed nonsm., Pe:	0.1881
Number of nonsmokers, N:	74,201,000
Working life, years:	45
Incidence rate in unexp., Iu:	0.00011373
Incidence rate in exp., Ie:	0.00015239
Due to ETS:	
No. of cases per year, Nets:	540
Annual no. of cases per 1000	
workers, Rets ann.:	0.00727
No. of cases per 1000 workers	
in lifetime, Rets Lifet.:	0.32725

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OSHA PRELIMINARY QUANTITATIVE RISK ASSESSMENT

Relative risk, RR:	1.34
Extent of exposure rel. to home:	1
Corrected relative risk, RRc:	1.3400
Incidence in total population Ip:	0.0001210
Proporation of exposed nonsm., Pe:	0.4867
Number of nonsmokers, N:	74,201,000
Working life, years:	45
Incidence rate in unexp., Iu:	0.00010382
Incidence rate in exp., Ie:	0.00013912
Due to ETS:	
No. of cases per year, Nets:	1,275
Annual no. of cases per 1000 workers, Rets ann.:	0.01718
No. of cases per 1000 workers in lifetime, Rets Lifet.:	0.77281

WORKPLACE EXPOSURE TO ENVIRONMENTAL TOBACCO SMOKE

OSHA uses Dobson, et al. as a positive study:

MALES   0.95 (0.51 - 1.78)

FEMALES   0.66 (0.17 - 2.62)

The authors state, "...passive smoking did not suggest increased risk."

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